

REMARKS

Claims 1-16 are pending in this application. Claims 1, 12, and 14 have been amended.

Claim 14 was rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner stated that the phrase "including" rendered the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim 14 as amended clarifies that the cholesterol is found in the food and that the composition comprises food and a food additive. This rejection should now be overcome.

Claims 1-16 were rejected under 35 U.S.C. 103(a) as being unobvious over Straub (U.S. 5,244,887). Applicants respectfully traverse this rejection.

Straub discloses a method for making a food additive composition comprising a stanol, an edible solubilizing agent, an effective amount of a suitable antioxidant, and an effective amount of a suitable dispersant. The stanol can be sitostanol. The solubilizing agents disclosed are vegetable oil, monoglycerides, diglycerides, triglycerides, tocopherols, and the

like. Dispersing agents disclosed are lecithin, other phospholipids, sodium lauryl sulfate, fatty acids, salts of fatty acids, fatty acid esters, and other detergent-like molecules. The Straub invention is intended for use in decreasing cholesterol absorption from only the food to which it is added (col. 3, lines 19-23).

Claim 1 has been amended to emphasize and clarify that the composition is in solid form and water soluble. Thus, claim 1 has the following limitations: solid; water-soluble; aqueous, homogenous micellar mix of plant sterol and an emulsifier from the specified class; dried to a finely-divided powder; and a mole ratio of sterol:emulsifier of 1:0.1 to 1:10. Missing from the Straub teaching is anything about the composition having any of the above listed limitations. All of these distinctions make the difference between a practical and usable delivery system suitable for mixing with foods, so that the food product itself is not impaired in any way, and so that the plant sterol is in a form which is in fact deliverable in dose form to provide its practical benefit for the human being, i.e., successfully lowering cholesterol levels. Claims 2-11 depend from claim 1. Claim 12 already includes the limitations of being finely-divided, water-soluble, and a dried powder (i.e., solid). Claim

13 is dependent on claim 12. Claim 14, like claim 1, has been amended to emphasize and clarify that the food additive is solid, water-soluble, finely-divided, homogeneous, and micellar. Claims 15-16 depend from claim 14.

These distinctions are emphasized in the Applicant's specification and provide unobvious results not foreseen by the prior art. For example, on page 5 it is emphasized that the aqueous vesicular complex of the micellar phase is highly bioavailable. Finely-divided, water-soluble is emphasized on page 5 where it is indicated that such a form can be easily ingested. Likewise, it is emphasized on page 5 that when this aqueous, soluble system is in contact with aqueous, soluble materials in the human digestive system, the aqueous, micellar complex enters directly into the intestinal micellar phase to inhibit cholesterol absorption. At page 6 of the application, it is emphasized that this system can be successfully dried, and surprisingly, the physical structure of the micelles are not destroyed. Put another way, even after drying they achieve their advantages when again exposed to an aqueous system in the human digestive system. In short, this specification goes to great length to indicate the importance of the claimed features not disclosed in the art, and to explain these limitations are

meaningful to provide unexpected advantages over the system taught by Straub.

The examples further emphasize their differences with meaningful data. Example 6 shows the greater effectiveness of the use of sodium stearyl-2-lactylate (SSL) as the emulsifier over any of the other standard emulsifiers, such as those listed in Straub, and comparable effectiveness to the parent application's use of a combination of lecithin and lysolecithin. Further, on page 5, lines 17-18, the specification points out that the SSL emulsifier is better than phospholipids in this water-soluble application due to water solubility in excess of 90%. This greater effectiveness of SSL is not taught, suggested or motivated by the prior art. The prior art teaches that the choice of the emulsifier is unimportant.

The mole ratio of plant sterol to emulsifier indicated in claims 1-3, 12, and 14 are not taught, suggested, or motivated by Straub. Straub teaches nothing about the ratio of stanol to dispersing agent.

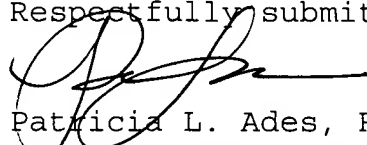
The prior art teaches, suggests or motivates nothing in regard to vesicles as claimed in claim 4. The Straub disclosure is an evenly distributed dissolution or suspension of the stanols in an emulsion (col. 6, lines 5-9).

Claim 12 includes a dosage limitation of 100 mg to 1000 mg sitostanol. Since the Straub invention is not intended as a therapeutic but is instead solely a food additive (col. 3, lines 19-23), Straub teaches or suggests nothing related to dosages. One would not be motivated to modify Straub as to get the daily dosages of the present invention.

Based on the foregoing, Applicants respectfully submit that pending claims are in condition for allowance at this time, as they are patentably distinguishable over the prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-3667 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitation in the present application which will be effective to define the patentable subject matter if the present claims are not deemed adequate for this purpose.

Respectfully submitted,



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